

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

BOULT WADE TENNANT
Attn. Baldock, Sharon C.
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT
UNITED KINGDOM

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference

SCB63541WO00

Date of mailing
(day/month/year)

23/09/2004

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/GB2004/002714

International filing date
(day/month/year)

24/06/2004

Applicant

GW PHARMA LIMITED

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Josef Ullrich

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference SCB63541W000	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, Item 5 below.</small>	
International application No. PCT/GB2004/002714	International filing date (day/month/year) 24/06/2004	(Earliest) Priority Date (day/month/year) 24/06/2003
Applicant GW PHARMA LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box II).

3. ☐ Unity of invention is lacking (see Box III).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

PHARMACEUTICAL COMPOSITIONS COMPRISING CABBINOCHEME TYPE COMPOUNDS

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

☐ as suggested by the applicant.

☒ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB2004/002714

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D311/20 A61K31/353

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BEILSTEIN Data, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/26728 A (IMMUGEN PHARMACEUTICALS INC ; TRAVIS CRAIG R (US)) 4 April 2002 (2002-04-04) the whole document	1-18
P, X	WO 2004/016254 A (IMMUGEN PHARMACEUTICALS INC ; TRAVIS CRAIG R (US)) 26 February 2004 (2004-02-26) the whole document	1-18
X	US 4 837 228 A (ELSOHLY MAHMOUD ET AL) 6 June 1989 (1989-06-06) the whole document	1-18
P, X	US 2003/232101 A1 (TRAVIS CRAIG R) 18 December 2003 (2003-12-18) the whole document	1-18
	-/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

13 September 2004

Date of mailing of the international search report

23/09/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Deutsch, W

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/002714

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GAONI Y ET AL: "THE ISOLATION AND STRUCTURE OF 1-TETRAHYDROCANNABINOL AND OTHER NEUTRAL CANNABINOIDS FROM HASHISH" 1971, JOURNAL OF THE AMERICAN CHEMICAL SOCIETY, AMERICAN CHEMICAL SOCIETY, WASHINGTON, DC, US, PAGE(S) 217-224 , XP001095011 ISSN: 0002-7863 the whole document	1-18
X	CA 2 322 549 A (SUTHERLAND MARTIN D ; HORNBY A PAUL (CA); DIMOTOFF PAVEL U (CA)) 27 March 2002 (2002-03-27) the whole document	1-18
X	US 6 328 992 B1 (BROOKE LAWRENCE L ET AL) 11 December 2001 (2001-12-11) the whole document	1-18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB2004/002714

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0226728	A	04-04-2002	AU 1342902 A	08-04-2002
			WO 0226728 A2	04-04-2002
			US 2003171372 A1	11-09-2003
			US 2002068738 A1	06-06-2002
WO 2004016254	A	26-02-2004	WO 2004016254 A2	26-02-2004
US 4837228	A	06-06-1989	US 4315862 A	16-02-1982
US 2003232101	A1	18-12-2003	WO 03080043 A1	02-10-2003
CA 2322549	A	27-03-2002	CA 2322549 A1	27-03-2002
US 6328992	B1	11-12-2001	US 6113940 A	05-09-2000
			AU 6554001 A	07-03-2002
			CA 2356020 A1	05-03-2002
			EP 1186298 A2	13-03-2002

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43b/s.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/002714

International filing date (day/month/year)
24.06.2004

Priority date (day/month/year)
24.06.2003

International Patent Classification (IPC) or both national classification and IPC
C07D311/20, A61K31/353

Applicant
GW PHARMA LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Deutsch, W

Telephone No. +49 89 2399-8281



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/002714

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/002714

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/002714

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 14,15 in respect of industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 14,15 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|------------------------------------------------------------|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/002714

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-18
Inventive step (IS)	Yes: Claims	
	No: Claims	1-18
Industrial applicability (IA)	Yes: Claims	1-13, 16-18
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

III

For the assessment of the present claims 14 and 15, on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Claims 14 and 15 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

V and VI

Reference is made to the following documents:

- D1: WO 02/26728 A (IMMUGEN PHARMACEUTICALS INC ; TRAVIS CRAIG R (US)) 4 April 2002 (2002-04-04)
- D2: WO 2004/016254 A (IMMUGEN PHARMACEUTICALS INC ; TRAVIS CRAIG R (US)) 26 February 2004 (2004-02-26)
- D3: US-A-4 837 228 (ELSOHLY MAHMOUD ET AL) 6 June 1989 (1989-06-06)
- D4: US 2003/232101 A1 (TRAVIS CRAIG R) 18 December 2003 (2003-12-18)
- D1: US-B-6 328 9921 (BROOKE LAWRENCE L ET AL) 11 December 2001 (2001-12-11)
- D5: GAONI Y ET AL: "THE ISOLATION AND STRUCTURE OF 1-TETRAHYDROCANNABINOL AND OTHER NEUTRAL CANNABINOIDS FROM HASHISH" 1971, JOURNAL OF THE AMERICAN CHEMICAL SOCIETY, AMERICAN CHEMICAL SOCIETY, WASHINGTON, DC, US, PAGE(S) 217-224 , XP001095011 ISSN: 0002-7863
- D6: CA-2 322 549 (SUTHERLAND MARTIN D ; HORNBY A PAUL (CA); DIMOTOFF PAVEL U (CA)) 27 March 2002 (2002-03-27)
- D7: US-B-6 328 9921 (BROOKE LAWRENCE L ET AL) 11 December 2001 (2001-12-11)

Novelty

The compound of example 10 differs from those of formula 1 according to claim 1 of the application through the length of the R^3 group. However the claims include derivatives of the compounds of formula 1, such that this example together with the disclosures on page 9, lines 19- page 14, line 16 is novelty destroying to the present claim.

The claims of D1 include both compounds overlapping directly with the compounds of formula 1 in the present claims as well as compounds which anticipate derivatives of the formula 1 compounds. This together with disclosures of pharmaceutical compositions of these compounds (see above paragraph and claim 13) is novelty destroying to the present claims.

The pharmaceutical compositions of D1 may also be formulated e.g. for topical formulations (see page 10, 2nd para of D1), such that claim 11 is also not novel.

The compositions of D1 also include antianxiety agents associated with mental depression (see page 13 of D1), such that claim 13 to 17 are anticipated by D1.

The compounds of formula 1 in the present differ from those of claim 1 D3 in that they are chroman type compounds, whereas the compounds of claim 1 of D3 are chromene derivatives (see double bond in the six membered oxygen containing ring). In this respect however the lack of clarity objection concerning whether the formula 1 compounds are intended to include chromen derivatives in section VIII is to be noted.

Since, the compounds of formula 1 of the present claims also include derivatives, the present claims are considered to be anticipated by claim 1 of D3. Derivatives would also include unsaturated forms of the compounds of formula 1.

Compounds (IV) and (X) (column 3 of D3) together with the disclosure in column 3, lines 19-36 of column D3 is novelty destroying to the present claims.

Table I of D5 shows the components of hashish includes cannabichromene, This together with the fact that cannabis has been used as a medicine (see first paragraph of D5) results in the disclosures of D5 being novelty destroying to the present claims.

D7 discloses that cannabis contains cannabichromene (see column 1, lines 23-26. and column 2, line 45 -53) and lists certain medicinal uses of cananabbis including depression and further a method of treating a patient with a transdermal cannabis preparation. These disclosures are novelty destroying to the present claims). Similarly D6, which disclose the use of cannabis in treating depression and anxiety is considered to be novelty destroying to the present claims.

Inventive Step

D7 is considered to be the closest prior art.

In view of the disclosures of D6 or D7, it is considered that the skilled person could have readily arrived at the claimed compositions, in particular he /she would have expected the claimed compositions to be useful in the treatment of mood disorders and depression.

The problem underlying the application is therefore considered to be the provision of compositions having surprising effect compared to the closest prior art.

In the absence of any surprising effect with respect to D6 an inventive step cannot be acknowledged.

certain cited documents

For the purposes of this communication it has been assumed that the priority of the present application is valid.

D2 and D5 do not constitute prior art within the meaning of Rule 64.1 (b).

VIII

- A) The term "derivative" indicated in the claims leads to an unclear scope of claim intended.

The term "derivative" in connection with compounds includes compounds obtained from another compound by a chemical reaction. Therefore compounds of formula 1 in the claims include open forms, structures which are structurally remote from

the compounds of formula 1, functional derivatives, compounds wherein the heteroatoms are exchanged by alternative atoms, compounds with numerous different types of side groups etc.

Having regard for the desired activities it is not considered that that all such derivatives would have the desired activities and that it is intended to claim all such structures. It remains unclear which actual structures are being claimed and where the borders lies.

- B) In the description on page 4, the following has been indicated "the cannabichromene or canabichromene type compounds" of formula 1 included in the invention may be naturally occurring or synthetic compounds.

It is further indicated "Natural cannabichromenes include cannabichromene (CBC) Formula 2) and cannabichromene propyl analogue (CBC-V) (formula 3)".

Inspection of formula 1 (see also the claims) and formulae 2 and 3 shows that they are not actually cannabichromene or cannabichromene type compounds, since a double bond is missing in the 6-membered oxygen containing fused ring. In this respect the correct structure of cannabichromene is given in D5, page 218, column 1, formula Va (cf double bond between positions 7 and 8).

It is therefore unclear, whether there is an error in the depiction of the claimed compounds.

- C) It is considered to be unclear, which compositions in claim 1 are excluded by the expression "smoked cannabis".

